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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,619	PLATTEEUW ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-9 and 11-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7-9 and 11-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 7-9, 11-20, 22-34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 6,328,994, in view of Sherwood et al. US 5,585,115.

Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% crystalline cellulose, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Active material includes omeprazole, and is coated with an enteric polymer (column 5, lines 14-24). Crystalline cellulose includes microcrystalline cellulose (MCC) (column 10, lines 13-24). Shimizu also teaches the tablet exhibits hardness of about 1-20 kg, and an oral disintegration time of about 30 second or less (column 12, lines 42-51).

Shimizu does not teach the use of the claimed microcrystalline cellulose.

Sherwood teaches an excipient suitable for pharmaceutical tablet formulation comprising (MCC) having average particle size from about 10 μm to about 1000 μm, and from about 0.1% to about 20% silicon dioxide content (abstract; column 5, lines 1-44; and column 11, lines 1-18). Sherwood further teaches the use of up to 70% of the

MCC as an excipient in a tablet dosage form (examples 10-12). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Shimizu using the MCC in view of the teaching of Sherwood to obtain the claimed invention, because Sherwood teaches an MCC that improved compressibility, because Sherwood teaches an MCC that possesses excellent disintegration and dissolution properties, and because Shimizu teaches the desirability of obtaining a direct compressed tablet that is useful for orally disintegrable administration.

Claims 1, 5, 7-9 and 11-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betzing et al. US 5,776,492, in view of Sherwood et al. US 5,585,115 and Shimizu et al. US 6,328,994.

Betzing teaches a rapidly disintegrating binder-free tablet comprising microcrystalline cellulose and tramadol in a ratio of at 2:1 (abstract). Examples 1-5 showed the use of about 70% MCC, tablet hardness of 60-80N, and disintegration time of 30-55 seconds. Betzing further teaches the use of other additives (examples).

Betzing does not teach the use of the claimed microcrystalline cellulose.

Sherwood teaches an excipient suitable for pharmaceutical tablet formulation comprising (MCC) having average particle size from about 10 μm to about 1000 μm, and from about 0.1% to about 20% silicon dioxide content (abstract; column 5, lines 1-44; and column 11, lines 1-18). Sherwood further teaches the use of up to 70% of the MCC as an excipient in a tablet dosage form (examples 10-12). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Betzing

using the MCC in view of the teaching of Sherwood to obtain the claimed invention, because Sherwood teaches an MCC that improved compressibility, because Sherwood teaches an MCC that possesses excellent disintegration and dissolution properties, and because Betzing teaches the desirability of obtaining a rapidly disintegrable tablet having tablet hardness and disintegrating time suitable for pharmaceutical use.

Betzing further does not explicitly teach the tablet is orally disintegrable.

Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% MCC, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Shimizu further teaches an oral disintegration time of about 30 second or less (column 12, lines 42-51). Thus, it would have been obvious to one of ordinary skill in the art to prepare an orally disintegrable tablet in view of the teaching of Shimizu, because Shimizu teaches an orally disintegrable tablet that can easily be administered without the need of water, which can be used for treatment of various diseases to the aged or children (abstract).

Response to Arguments

Applicant's arguments filed 07/12/07 have been fully considered but they are not persuasive.

Applicant argues that unlike the presently claimed invention, Shimizu uses significantly less than 50% of a microcrystalline cellulose-type binder.

However, in response to applicant's argument, it is noted that Shimizu teaches the use of MCC in an amount of up to 50% (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Further, Shimizu is cited in view of Sherwood for the additional teaching of the claimed amount of MCC. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Shimizu is a relatively slow orally disintegrating tablet. While generically teaching a preferred oral disintegration time (measured in the adult mouth and not *in vitro* as per the present invention) of "more preferably about 30 seconds or less," the fastest example achieves oral disintegration in 20 seconds. (See col. 12, lines 42-47 and Example 4.)

However, in response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., disintegration time measured *in vitro*) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they

contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.). Thus, the teaching of Shimizu cannot be limited to his best mode as described in the examples.

Applicant argues that nothing in Shimizu or Sherwood would suggest the use of the Applicant's claimed at least 50 wt.% of silicified MCC. Replacing the MCC in Shimizu with silicified MCC, which the Examiner's purports to have been obvious, would result in too little silicified MCC in order to meet Applicant's claim 1. The fact that Sherwood teaches tablets having greater amounts of silicified MCC is irrelevant because those tablets are not orally disintegrating. There is no motivation to combine the teachings of Shimizu and Sherwood to obtain the Applicant's claimed orally disintegrating tablet containing at least 50 wt.% of silicified MCC.

In response to applicant's argument that Sherwood teaches tablet that is not orally disintegrating, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Further, it is noted that the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the

prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Sherwood teaches the use of MCC in tablet formulations is known in pharmaceutical art. Further, Sherwood teaches using MCC in tablet formulations helps improve compressibility, possesses excellent disintegration and dissolution properties. For the same token, Shimizu teaches the desirability of obtaining a direct compressed tablet that is useful for orally disintegrable administration.

Applicant argues that Shimizu and Sherwood do not provide a reasonable expectation of achieving the Applicant's disintegration time of 1-15 seconds. Note that Shimizu's measured disintegration is based on an oral administration. As explained on page 6 of the present specification, generally the *in vitro* disintegration test times are somewhat longer than the orally experienced time for disintegration. Shimizu's tablets if tested in the Applicant's defining *in vitro* disintegration test would likely yield slightly longer times than as reported in Shimizu e.g., longer than 20 seconds. Nothing in Shimizu or Sherwood teaches the reader how to improve these disintegration times. And certainly nothing in Sherwood teaches or suggests that silicified microcrystalline cellulose would be useful in improving oral disintegration times.

However, as discussed above, the present claims do not require the disintegration time to be measured as *in vitro* disintegration time. Moreover, Shimizu

does teach the claimed disintegration time, namely, oral disintegration time of about 30 second *or less* (column 12, lines 42-51).

Applicant argues that Betzing teaches rapidly disintegrating tablets comprising MCC. The tablets, however, disintegrate significantly slower than the presently claimed orally disintegrating tablets. As shown in the Table in column 5 of Betzing, the fastest tablets disintegrated in 25-30 seconds. Other Betzing inventive tablets disintegrated in the 100-110 second range. This is not too surprising given that Betzing intends to form a suspension of the disintegrated tablet in a liquid prior to administration (See col. 2, lines 61-65). While one to two minutes is sufficiently rapid for a tablet to disintegrate in a glass of water before drinking, such lag time is not desired in an orally disintegrating tablet that may be placed directly into the mouth.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Betzing is cited in view of Shimizu for the teaching of orally disintegrable time.

Applicant argues that there is no motivation to combine Betzing with Shimizu and Sherwood.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Sherwood teaches the use of MCC helps improve compressibility, possesses excellent disintegration and dissolution properties. Betzing teaches the desirability of obtaining a rapidly disintegrable tablet having tablet hardness and disintegrating time suitable for pharmaceutical use. Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% MCC, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Shimizu further teaches an oral disintegration time of about 30 second or less (column 12, lines 42-51). Thus, it would have been obvious to one of ordinary skill in the art to prepare an orally disintegrable tablet in view of the teaching of Shimizu, because Shimizu teaches an orally disintegrable tablet that can easily be administered without the need of water, which can be used for treatment of various diseases to the aged or children (abstract).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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